

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 4308PTWO/RA/a	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/00519	International filing date (day/month/year) 17.01.2003	Priority date (day/month/year) 01.02.2002
International Patent Classification (IPC) or both national classification and IPC A61K31/13		
Applicant GIULIANI S.P.A.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 24.07.2003	Date of completion of this report 06.02.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Beeck, M Telephone No. +49 89 2399-8473 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EP 03/00519**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-12 as originally filed

Claims, Numbers

1-8 received on 22.01.2004 with letter of 19.01.2004

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-7
	No: Claims	8
Inventive step (IS)	Yes: Claims	1-7
	No: Claims	8
Industrial applicability (IA)	Yes: Claims	1-8
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP03/00519

- D1: P.I.HYND, M.J.NANCARROW: 'Inhibition of polyamine synthesis alters hair follicle function and fiber composition' JOURNAL OF INVESTIGATIVE DERMATOLOGY, vol. 106, no. 2, 1996, pages 249-253, XP008006126
- D2: WO 96 23490 A (COSMEDERM TECHNOLOGIES) 8 August 1996 (1996-08-08)

- 1) Document D1 is the closest prior art for claims 1 to 4 stating that spermidine plays a major role in **hair growth** (see the abstract, last sentence).

However, the person skilled in the art could not expect from this statement that spermidine would also be active against **hair loss**.

Therefore the subject-matter of claims 1 to 4 involves an inventive step.

- 2) However, lotions or balms containing spermidine are already known from document D2 (see example 1 and claims 2, 46 and 48).

Therefore the subject-matter of claim 8 is not novel (Article 33 (2) PCT).

- 3) The subject-matter of claims 5 and 6 differs from document D2 in that it contains further additives which were not obvious for the person skilled in the art.

The subject-matter of claim 7 differs from D2 in that it is a formulation for oral use which was not obvious either.

Therefore the subject-matter of claims 5 to 7 also involves an inventive step.

AMENDED CLAIMS

1. Use of spermidine as an active principle in the preparation of a composition for pharmaceutical or dietetic use in man to combat hair loss.

2. Use of spermidine according to Claim 1, to combat hair loss in the case of the pathology known as telogenic defluvium.

3. Use of spermidine according to Claim 2, to reduce the telogenic phase in the growth cycle of the hair.

4. Use of spermidine according to Claim 1, to make the hair robust.

5. Composition for pharmaceutical or dietetic use to be administered to man to combat hair loss, characterized in that it comprises methionine, vitamin C, polyphenols, vitamin E, calcium pantothenate, zinc (as amino acid chelate), vitamin B₆, copper (as amino acid chelate), folic acid and biotin.

6. Composition according to Claim 5, characterized in that it comprises:

Methionine	300.00	mg.
Vitamin C	90.00	mg
Polyphenols from <i>Vitis vinifera</i>	5.00	mg
Vitamin E	15.00	mg
Calcium pantothenate	9.00	mg
Zinc (as amino acid chelate)	7.50	mg
Vitamin B ₆	2.00	mg
Copper (as amino acid chelate)	1.25	mg
Spermidine	0.50	mg
Folic acid	0.15	mg
Biotin	0.05	mg

7. Composition for pharmaceutical or dietetic use to be administered to man to combat hair loss, characterized in that it is formulated for oral administration and comprises an oral vehicle and spermidine as active principle.

8. Lotion or balm to be applied to the human scalp to make the hair robust and to reduce hair loss characterized in that it comprises spermidine as active principle.